UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

THE ADMINISTRATOR

March 19, 2001

MEMORANDUM

TO: Stephen L. Johnson, Acting Assistant Administrator
Office of Prevention, Pesticides, and Toxic Substances

FROM: Christine Todd Whitman, Administrator

SUBJECT: Directive on Implementation of EPA Obligations Under the Consent Decree in NRDC v. Whitman

I consider EPA's programs of pesticide reregistration and tolerance reassessment to be critical parts of EPA's overall mission to protect public health and the environment. Therefore, we must make every effort to meet the next statutory deadline to reassess 66% of existing tolerances by August 3, 2002. At the same time, there has been tremendous public interest in the manner in which EPA intends to conduct pesticide reregistration and tolerance reassessment activities, particularly in light of the Consent Decree negotiated with NRDC in January of this year.

EPA staff has met with the Department of Agriculture, industry, agricultural, and animal rights interveners in the NRDC v. Whitman litigation, NRDC, and others to discuss the best way of implementing the Agency's obligations under the Consent Decree. This Directive is in response to a number of the concerns raised in those meetings. The Agency also negotiated modifications to the Consent Decree to address some of these concerns. It is my goal for the Agency to conduct reregistration and reassessment activities in an open and transparent manner, with ample opportunities for public participation, and to make all regulatory decisions based upon principles of sound science. It is my belief that the Consent Decree is consistent with these goals, and I want to assure that the Consent Decree be implemented with these goals in mind. To that end, I am hereby directing the Office of Prevention, Pesticides, and Toxic Substances to do all of the following in conducting its reregistration and reassessment activities under the Decree:

- The Office of Pesticide Programs (OPP) will use a variety of means to engage the public in discussion on the best means of optimizing public participation in the conduct of the activities covered by the Consent Decree. These will include using the Committee to Advise on Reassessment and Transition (CARAT), either in full sessions or in workgroups, as well as other appropriate methods. I believe that the Consent Decree

allows for active public participation in these activities, and I want these activities conducted in a manner that fosters active public participation.

- In conducting risk assessments and in making regulatory determinations related to tolerance reassessment and pesticide reregistration, I want EPA to consider label changes and other changes to the terms and conditions of pesticide registration to the extent that there is adequate information to assess the effects of such changes upon the risk assessment or regulatory determination.

- In determining under Paragraph 9 of the Consent Decree whether the risks to workers from use of a pesticide constitute unreasonable adverse effects on the environment, the Agency will apply the risk/benefit standard in the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), taking into account the economic, social, and environmental costs and benefits of the use of the pesticide.

- EPA will hold a meeting of its FIFRA Scientific Advisory Panel (SAP) to review the Office of Pesticide Program's (OPP) analysis of toxicity data on the organophosphate (OP) pesticides to determine "relative potency factors." This meeting will be held prior to issuance of the preliminary cumulative risk assessment for the OP pesticides, scheduled under the Consent Decree for no later than December 1, 2001.

- During this SAP meeting, EPA will provide sufficient time for interested members of the public to make substantive presentations.

- If the SAP concludes at or after this meeting that OPP's approach to determining the relative potency factors for the OP pesticides contains significant methodological flaws, or disagrees with OPP's premise that the available toxicity data are sufficient to support such determinations, or identifies other significant scientific flaws in OPP's approach such that the Agency must fundamentally alter its risk assessment approach or resource commitment to conduct the OP cumulative risk assessment, EPA will consider whether to invoke the provisions of paragraph 5 of the Consent Decree and revise the cumulative risk assessment schedule.

- In response to concerns that have been raised by some about the adequacy of the existing toxicity database EPA will use in developing relative potency factors for use in a cumulative risk assessment for OPs, and in light of the interest that has been expressed in developing new toxicity studies of the organophosphate pesticides to better develop relative potency factors, EPA will review and comment on any proposed protocol for conducting such new toxicity studies, and will suggest any changes to the protocol the Agency considers necessary. EPA will provide its response in writing within 45 days of receipt of a written protocol. If EPA and the submitters of the protocol disagree about the most appropriate manner of conducting such studies, EPA will work in good faith with the submitters to resolve any areas of disagreement.

- EPA will identify a date by which new toxicity studies must be submitted in order to allow for timely review prior to completion of the cumulative risk assessment for the

OPs, and will commit to review and incorporate, as appropriate, the new data in its revised cumulative risk assessment for the OPs. If the new toxicity data are submitted later than that date, OPP will use its best efforts to complete their review and to include them appropriately in the revised cumulative risk assessment, consistent with meeting the schedule set forth in the Consent Decree.

- As now provided in the Consent Decree, EPA will provide a sixty (60) day period for public comment on the preliminary cumulative risk assessment for the OPs.

- EPA will consider new data in the development of its Reregistration Eligibility Decision (RED) and interim RED (IRED) documents, provided the data are submitted sufficiently in advance of the issuance of the RED or IRED document to allow EPA adequate time to review and incorporate the data appropriately, consistent with meeting the schedules set forth in the Consent Decree.

- If any person identifies a particular new study that he/she wants to submit for consideration in the development of a risk assessment, RED, or IRED identified in the Consent Decree, and identifies the date by which the study will be submitted, EPA will inform the person whether the proposed submission date provides the Agency with sufficient time to review and consider the data in developing the risk assessment, RED, or IRED and, if the proposed submission date does provide sufficient time, EPA will commit to reviewing and considering the data in its development of the risk assessment, RED, or IRED. Where the Agency concludes that the proposed submission date may not provide sufficient time to allow its review and consideration in the development of a document identified in the Consent Decree under the time frames set forth in the Decree, EPA will use its best efforts to review and consider the data to the extent that such data may be considered consistent with meeting the schedules set forth in the Consent Decree.

- When issuing each of the four "common mechanism" determinations required under the Consent Decree, EPA will solicit public comment on its determination and will revise such determinations if the public comments or other sources provide new data or present new approaches to the examination of existing data that warrant modification of the Agency's initial determination.

- As now provided in the Consent Decree, when determining whether a class of pesticides share a common mechanism of toxicity, EPA will either follow written policies pertaining to common mechanism determinations that are current at the time of the particular determination, or EPA will include in writing in the determination a description of any deviations from current common mechanism policy and an explanation of why we believe such deviations are appropriate.

- As now provided in the Consent Decree, EPA, to the extent permitted by law, will use its best efforts to make the toxicity studies that are being relied upon in the conduct of the preliminary and revised cumulative risk assessments for organophosphates available to the public within forty-five (45) days of entry of this Consent Decree or, if a study is submitted after entry of this Decree, within forty-five (45) days of the Agency's receipt

of the study. In making these studies available to the public, EPA will request that the submitters of such studies make such arrangements as are necessary to allow the studies to be available to interested pesticide producers notwithstanding the provisions of section 10(g) of FIFRA. EPA will make available to the public its analyses of relative potency factors for use in the preliminary risk assessment on or before July 31, 2001.

- As now provided in the Consent Decree, when an assessment of pesticide benefits is included in a reregistration document issued pursuant to the Decree, EPA will provide an opportunity for public comment on the benefits assessment either by publication of the assessment on the Office of Pesticide Programs' Internet Website or by specifically providing in the reregistration document a sixty (60) day opportunity for public comment on the benefits assessment.

Please continue to work with stakeholders on these and other issues related to pesticide reregistration and tolerance reassessment, and provide me with an update on the implementation of this Directive in four months.

MODIFICATIONS TO CONSENT DECREE

After consultation with the Department of Agriculture and representatives of the farming and pesticide manufacturing community, a number of modifications have been made to the Consent Decree negotiated with NRDC :

- Specific language has been inserted providing that, in developing relative potency factors (RPF) for use in a cumulative risk assessment for the organophosphates, EPA will make its RPF analyses available to the public by July 31, 2001; EPA will make the underlying toxicity studies available to the public to the extent possible under FIFRA (multinational pesticide producers can only get access to the studies to the extent that the submitters of the studies acquiesce); and EPA will agree to work with companies that wish to generate additional toxicity studies in order to clarify how the studies could best be performed.

- Specific language has been inserted providing for a public comment period after issuance of a draft cumulative risk assessment for the organophosphates.

- The Agency has clarified in the Consent Decree that it intends to consider label changes and other changes to the terms and conditions of a pesticide's registration when conducting a risk assessment for a pesticide.

- EPA has clarified in the Consent Decree that it intends to provide opportunities for public participation in its tolerance reassessment and pesticide reregistration activities, and that it intends to discuss the timing and nature of such opportunities with its Committee to Advise on Reassessment and Transition (CARAT).

- EPA has also clarified in the Consent Decree that it intends to consider new data in the development of risk assessments and reregistration eligibility determinations if the new data are submitted sufficiently before the scheduled date of issuance of the assessment or determination to allow for thorough review and consideration of the new information.

- Four months have been added to the scheduled date for the Interim Reregistration Eligibility Determination for phosmet in order to allow the Agency to better coordinate its analyses of pesticide benefits with USDA.

- Specific language has been added to the Decree providing that, when determining whether chemical compounds share a common mechanism of toxicity, EPA will follow its existing policies or explain, in writing, any deviations from such policies.

- Specific language has been added to the Decree providing that after it makes a determination as to whether chemicals in four specified classes of pesticides share common mechanisms of toxicity, EPA will accept public comment on the determinations and will consider the comments in any subsequent risk assessments involving the chemicals. [EPA could also issue revised determinations based upon the comments].